



www.biistate.net



BISNIS Search for Partners – Leads from the BioIndustry Initiative



INDUSTRY:
MEDICAL
EQUIPMENT AND
PRODUCTS,
PHARMACEUTICALS,
HEALTH CARE
SERVICES

COMPANY /
INSTITUTE:

State Research Center for
Applied Microbiology and
Biotechnology (SRCAM&B),
Obolensk, Moscow region
www.obolensk.org

COUNTRY: Russian
Federation

Contact the
BioIndustry
Initiative:

Maria Douglass
Deputy Program Director,
Accelerated Drug & Vaccine
Development
BioIndustry Initiative
www.biistate.net
EurasiaBio2006@biistate.net
tel. 1.703.298.1276

TEST-KIT FOR RAPID DRUG
SUSCEPTIBILITY TESTING OF *M.*
TUBERCULOSIS

ABSTRACT: Drug resistant tuberculosis is an increasing public health concern in many parts of the world, including Russia. Traditional drug susceptibility testing is often both time-consuming (21-28 days for the absolute concentration method) and expensive (automatic BACTEC systems). In contrast, the novel SRCAM test-kit yields results in 8-13 days. It is inexpensive and does not require the use of any additional equipment. This new method of drug susceptibility testing using the TB test-kit is based on the ability of *M. tuberculosis* to reduce nitrates to nitrites. The resulting nitrites are detected with Griess reagent, which produces a color change. Resistant isolates of *M. tuberculosis* produce color changes in the vial with containing the appropriate drug whereas susceptible isolates do not produce a color change. The TB test - kit allows the determination of susceptibility of *M. tuberculosis* to four main antibiotics: isoniazid, rifampicin, streptomycin, and ethambutol, and to perform primary identification of *M. tuberculosis*.

TYPE OF PARTNERSHIP OFFERED: The SRCAM TB Test-Kit offers many advantages of cost and time and can be used by mycobacterial laboratories worldwide. SRCAM&B is seeking potential investors and collaborations with U.S. Industry to commercialize the product

COMPANY / INSTITUTE ROLE: Licensing and partnership for commercialization, including provision of clinical datasets in support of regulatory approvals.

CURRENT STATE OF DEVELOPMENT: The SRCAM TB Test-Kit is currently being manufactured on a pilot scale and being tested in three clinical laboratories in Russia in comparison with the absolute concentration method and the BACTEC MGIT 960 using about one thousand *M. tuberculosis* isolates.

INTELLECTUAL PROPERTY STATUS: The TB test-kit is protected by the Russian Federation Patent No. 2268298 (priority date 16 October

2003;“The test - kit for rapid drug susceptibility testing and primary identification of *M. tuberculosis*”)

OTHER INFORMATION

Institute representatives will be attending BIO2006 (Chicago, April 9 – 12, 2006) and welcome the opportunity to meet with interested parties during the event. For more information: <http://www.biistate.net/docs/bio2006.php> or email: EurasiaBio2006@biistate.net

ABOUT INSTITUTE:

The State Research Center for Applied Microbiology & Biotechnology (www.obolensk.org) is part of the Russian Federal Surveillance Service in the field of public health. The mission of the Center is to carry out basic and applied research in epidemiology, bacteriology and biotechnology aimed at assuring the well-being for the population, as well as to manufacture biotechnological products at pilot and large-scale levels. The Center has the necessary infrastructure and skilled personnel to carry out research involving various bacterial pathogens, including those causing especially dangerous infections (anthrax, plague, tularemia, glanders, melioidosis, cholera). Recently, the animal facility for handling SPF laboratory animals (rabbits, hamster, mice and rats) has been renovated and there is an installation for studies involving inhalation challenge of animals.

R&D Highlights:

- Technology of revertase production, which received a State Award;
- Improved technologies of production of anthrax and typhoid fever vaccines;
- Russian technology for the production of human gene-engineered insulin;
- Bacterial formulations to control agricultural pests;
- Experimental mouse model of chronic/latent tuberculosis for testing new anti-tuberculosis drugs;
- NMR-relaxometer-analyzer "Proton-20" to control biotechnological processes;
- Theoretical works in the area of electro-orientation of particles, and as a result, new equipment for investigating cell populations on the basis of the electro-optic effect;
- Production of diagnostics and nutrient media;
- Non-pathogenic fungal and bacterial strains, collected from Russian national parks, capable of producing biologically active substances; and
- Five patents for developments made in SRCAM&B were sold to Russian companies in 2005

Nutrient Media Production

The Center is the premier producer of nutrient media for research in the Russian Federation. First initiated in 1993, the Laboratory of

Nutrient Media Design has increased its production 15-fold, and now provides a broad product line that meets over 50% of the demand for a variety of nutrient media in Russia, as well as in several other CIS countries. SRCAM has extensive experience in the development and large-scale production of media, including those used for isolation and cultivation of dangerous infection agents; socially significant infectious agents, such as the causative agents of tuberculosis; and for sanitary and clinical microbiology. All the products are designed at SRCAM. 20 nutrient media have patents of the USSR and Russia, 25 media products are registered in the Register of Medical Products of the Russian Federation and have certificates for manufacture. The products of SRCAM have been awarded with diplomas and medals at Russian exhibitions.

Recombinant Human Insulin Production

Research and development at SRCAM led to the successful production of a recombinant, human insulin-producing microorganism that resulted in the formation of the Joint Stock Company National Biotechnology, which is now commercially-producing active pharmaceutical ingredient for the Russian market. Center staff was instrumental in the initial research that produced the commercial strain, as well as the pilot and scale-up production engineering of the insulin.

MAJOR CUSTOMERS / INTERNATIONAL EXPERIENCE:

Over the past ten years, SRCAM&B has been cooperating with foreign research organizations, such as the ISTC, CRDF, INTAS programs, etc. Mutually beneficial relationships have been established with more than 70 organizations worldwide. A series of international seminars and conferences have also been conducted at the Center. SRCAM&B welcomes collaboration from Western Industry.

PARTNERSHIP OPPORTUNITIES FROM BII. The BioIndustry Initiative (BII) is a nonproliferation program of the US Department of State's Bureau of International Security and Nonproliferation - Office of Cooperative Threat Reduction (ISN-CTR). BII's mission is to counter the threat of bioterrorism through targeted transformation of former Soviet biological weapons research and production capacities.

DISCLAIMER. The leads are sourced by the BioIndustry Initiative through our partner organizations in Russia and other Eurasian countries. Leads are provided solely as an information resource and do not represent an endorsement by BII or the U.S. Departments of State and Commerce. Verification of the leads is the responsibility of the reader. Assistance conducting due diligence and negotiations with Eurasian companies/institutes may be provided in some cases. Contact BII for more details: bii@biistate.net.